

REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application are respectfully requested in light of the amendments above and the comments which follow.

As correctly noted in the Office Action Summary, claims 1-12, 15-16 and 41-55 were pending. By the present response, claims 1-4, 7, 41, 43, 47 and 55 have been amended and claims 56-64 have been added. Thus, upon entry of the present response, claims 1-12, 15-16 and 41-64 remain pending and await further consideration on the merits.

Support for the foregoing amendments can be found, for example, in at least the following locations in the original disclosure: paragraphs [0015], [0038], [0041], [0058], [0061], [0066], [0074], [0086], and [0102] - [0107]; and Figures 1a-1b.

Entry of the foregoing amendments is appropriate pursuant to 37 C.F.R. §1.116 or at least the following reasons. First, the foregoing amendments clearly act to place the application in condition for allowance. Second, the foregoing amendment reduces the number of issues present upon appeal.

Applicants wish to thank Examiner Ramana for the courtesies extended to applicants' representative during a personal interview conducted in the U.S. Patent and Trademark Office on September 3, 2009. During the interview, agreement was reached that the foregoing amendments would serve to overcome all of the current grounds for rejection under 35 U.S.C. §112. In addition, a productive exchange of views concerning the content of the applied prior art with respect to the requirements of the presently claimed invention was had. While no agreement was reached concerning patentability of the presently claimed invention over the applied prior art,

it is believed that the efforts made during the personal interview will ultimately lead to advancement of the prosecution of the present application and allowance thereof.

CLAIM REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claim 1-12, 15-16, and 47-50 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 1, the limitation, "said granules constituting a major weight fraction" is deemed to be new matter.

Applicants continue to believe that the limitation "said granules constituting a major weight fraction" does not constitute new matter, for at least the reasons already of record. However, in order to advance prosecution, the claims have been amended in a manner, without narrowing the scope thereof, which, has been agreed, overcomes the above-noted grounds for rejection. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1-12, 15, 16, 41-42, 47 and 51-55 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

While applicants do not concede that the identified claim language is in violation of the requirements of 35 U.S.C. §112, nevertheless in the interest of

compact prosecution, applicants have proffered the foregoing amendments which, as agreed during a personal interview of September 3, 2009, overcomes the grounds for rejection. Moreover, applicants do not believe that the foregoing amendments serve to narrow the scope of the presently claimed subject matter. Reconsideration and withdrawal of these rejections is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 43, 44 and 45 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 7,241,316 to Evans et al. (hereafter "*Evans et al.*") on the grounds set forth on page 3 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

The present invention is directed to compositions which are formulated such that they provide certain advantages and benefits for applications such as a moldable biocompatible implant. Compositions formed according to the principles of the present invention provide certain benefits and advantages relative to conventional biocompatible implant materials.

For example, calcium phosphate cements, which can be biodegradable, have been utilized as biocompatible implants. However, such materials often lead to the formation of dense or solid masses that inhibit osteo-conduction (see, e.g., paragraph [0006]; this is essentially the construction described by Ricci et al). Moreover, implants which are solid and contain only small pores can be disadvantageous in that the natural bone surrounding the implant cannot integrate into the implant unless the implant is degraded. Unlike an osteo-inductive and/or osteo-conductive implant, these implants have limited use for restoring the wound or

defect to a more natural condition, in other words they fill rather than heal the defect (see, e.g., paragraph [0007]; this is essentially the construction disclosed by *Evans et al.*).

A composite matrix formed according to the principles of the present invention as set forth in claim 43. Claim 43 recites:

*43. A composite matrix comprising:
a structural matrix, the structural matrix comprising
a plurality of biocompatible synthetic non-polymeric
granules bound together, at least in part, by a
biocompatible polymer coating formed on each granules;
and
an open porous region comprising macropores
between adjacent coated granules;
wherein the structural matrix does not contain any
bone particles.*

Evans et al. is directed to devices and methods for treating defects in the tissue of a living being. However, *Evans et al.* fails to anticipate the composite matrix set forth above in claim 43.

As evident from the above, claim 43 requires non-polymeric granules bound together, at least in part, by a biocompatible synthetic polymer coating formed on each granule, and an open porous region comprising macropores between adjacent coated granules.

By contrast, *Evans et al.* fails to disclose this form of composite structure. This point is illustrated by reference, for example, to the embodiment depicted in Figure 27 therein, which is reproduced below:

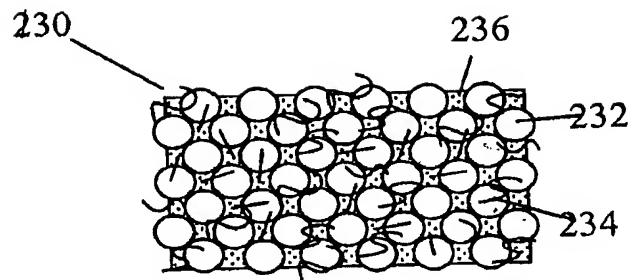


FIG. 27

As evident from the above, *Evans et al.* discloses a composite which includes a plurality of beads 232, and a continuous filler material 216 which completely fills the spaces between adjacent beads 232. Thus, nowhere does *Evans et al.* disclose a composite matrix which includes a plurality of biocompatible synthetic non-polymeric granules having a biocompatible synthetic polymer coating formed on each granule. Moreover, the composite disclosed by *Evans et al.* does not include an open porous region comprising macropores between adjacent coated granules.

Thus, for at least the reasons noted above, *Evans et al.* clearly fails to anticipate the composite matrix set forth in claim 43. Claims 44 and 45 depend from claim 43. Thus, *Evans et al.* fails to anticipate these claims for at least the same reasons noted above. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 43, 44 and 45 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 6,770,695 to Ricci et al. (hereafter "*Ricci et al.*") on the grounds set forth on page 3 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

The requirements of claim 43 have been noted above.

Ricci et al. discloses a time release calcium sulfate matrix for bone augmentation. However, *Ricci et al.* clearly fails to anticipate the composite matrix set forth in claim 43 above. *Ricci et al.* discloses a composite material, as depicted in Figure 1 therein, which is reproduced below:

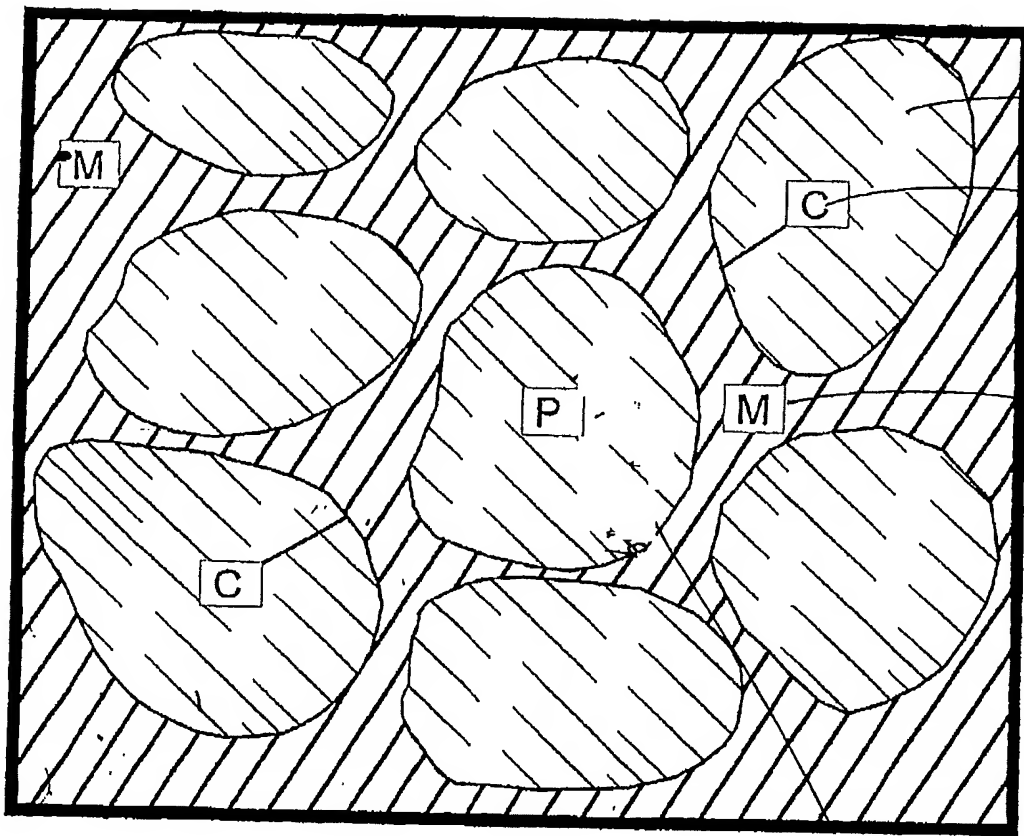


Fig. 1

As illustrated therein, the composite material includes a number of particles (P) which can comprise calcium sulfate. These particles can be provided with a polymer coating (C) a continuous matrix (M) is formed between adjacent coated particles (P), and is formed from a settable calcium sulfate compound. This

composite construction is essentially in the form of a calcium sulfate cement. Such materials are discussed in paragraph [0006] of the present specification. As disclosed therein, such materials disadvantageously lead to the formation of dense or solid formations that inhibit osteo-conduction.

As evident from the above, the particles (P) of *Ricci et al.* are not bound together, at least in part, by a biocompatible polymer, as required by claim 43. Instead, the coated particles (P) are bound together, entirely by the hard set calcium sulfate compound matrix (M). In addition, the composite structure of *Ricci et al.* clearly fails to include an open porous region comprising macropores between adjacent coated granules. In fact, the spaces between coated particles (P) is apparently replaced with granular tissue (G), bone growth (B), and calcium phosphate deposits (CP) upon degradation or absorption of the calcium sulfate compound matrix (M). See, e.g., Figures 2-4 of *Ricci et al.*

Thus, for at least the reasons noted above, *Ricci et al.* clearly fails to anticipate the composite matrix set forth in amended claim 43. Claims 44 and 45 depend from claim 43. Thus, these claims are also distinguishable over *Ricci et al.* for at least the same reasons noted above. Reconsideration and withdrawal of the rejection is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claims 1-3, 5-9, 11-12, 16, 41-42 and 46-55 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Ricci et al.* on the grounds set forth on page 4 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

A composition formed according to the principles of the present invention is set forth in amended claim 1. Amended claim 1 recites:

*1. A moldable implant composition for use in repairing a bone defect in a living organism, comprising:
a plurality of biocompatible synthetic non-polymeric granules, said granules having an equivalent diameter of about 100 μm to about 4,000 μm ;
a biocompatible polymer coating at least a portion of the implant mass comprising a composite matrix of the granules bound together by the biocompatible polymer and macropores between adjacent granules said granules so as to form an implant mass comprising a plurality of distinct granules coated with said biocompatible polymer, said biocompatible polymer comprising about 4% to about 20% of the total weight of the implant mass; and
a plasticizer in said implant mass in an amount sufficient to condition at least a portion of said biocompatible polymer so that said implant mass is initially plastically deformable into a desired shape and then hardenable upon removal of at least a portion of said plasticizer from said implant mass.*

As evident from the above, claim 1 requires composition which includes a plurality of distinct granules coated with a biocompatible polymer so as to form an implant mass. The implant mass is further defined as comprising a composite matrix of the granules bound together by the biocompatible polymer and micropores between adjacent granules. *Ricci et al.* fails to disclose at least these aspects of amended claim 1.

For reasons similar to those previously explained above, *Ricci et al.* discloses a composition in the form of a composite wherein coated granules are completely surrounded by a hard set matrix of calcium sulfate compound. See, e.g., Figure 1 of *Ricci et al.* Thus, *Ricci et al.* lacks a plurality of distinct granules coated with biocompatible polymer, and additionally lacks a configuration wherein the coated granules are bound together by the biocompatible polymer, or the presence of

macropores between adjacent granules. Moreover, nowhere does *Ricci et al.* even suggest that such a construction is either desirable or possible. Thus, *Ricci et al.* fails to disclose, or even suggest, the multiple implant composition recited in amended claim 1 for at least the reasons noted above.

A composite implant mass formed according to the principles of the present invention is set forth in amended claim 41. Amended claim 41 recites:

41. A composite implant mass comprising:
a structural component, the structural component comprising a plurality of biocompatible synthetic non-polymeric granules, the granules being regularly-sized, regularly shaped, or spherical, and the granules having an equivalent diameter of about 100 μm to about 4,000 μm ;
a biocompatible polymer on at least a portion of the granules; and
a plasticizer in an amount sufficient to condition at least a portion of the biocompatible polymer so that the granules of the implant mass are bound together by the biocompatible polymer and the implant mass is initially plastically deformable.

As evident from the above, claim 41 requires that the granules of the implant mass are bound together by the biocompatible polymer. As previously discussed, this is not the case with the composite material of *Ricci et al.* Instead, the coated particles (P) of *Ricci et al.* are entirely bound together solely by the hard settable calcium sulfate compound matrix (M). *Ricci et al.* fails to disclose, or even suggest, that such an implant mass construction is either possible or desirable. Thus, *Ricci et al.* fails to disclose, or even suggest, the implant mass recited in amended claim 41.

Moreover, claim 41 requires that the granules have an equivalent diameter of about 100 μm to about 4000 μm . Although acknowledging that *Ricci et al.* fails to disclose this aspect of the presently claimed invention, it is nevertheless asserted that it would have been obvious to one of ordinary skill in the art to have (optimized)

the particle size of *Ricci et al.* so as to lie within the claimed range. This assertion is respectfully traversed. First, it should be recognized that it is disclosed in the present specification that granules having a diameter within the claimed range are specifically selected so as to provide easy handling and processing. See, e.g., paragraph [0045] of the present specification. Moreover, such an "optimization" rationale is inappropriate where the applied prior art fails to recognize that the parameter being optimized is a result effective variable. Nowhere does *Ricci et al.* recognize that the particle size is a result effective variable. Thus, the grounds for rejection are improper for at least this additional reason.

The remaining claims depend from either claims 1 or 41. Thus, these claims are also distinguishable over *Ricci et al.* for at least the same reasons noted above.

Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over *Ricci et al.* in view of *Evans et al.* on the grounds set forth on page 5 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Evans et al. is cited as allegedly teaching the use of biocompatible ceramics such as calcium phosphate salts. It is then asserted that it would have been obvious to substitute a calcium phosphate salt for the calcium sulfate material disclosed by *Ricci et al.* This assertion is respectfully traversed. *Ricci et al.* is specifically targeted to solving the bio-absorption rate problem associated with calcium sulfate materials. In fact, *Ricci et al.* acknowledges the use of calcium phosphate ceramics in bone augmentation materials in the prior art, but specifically addresses calcium sulfate, which has different absorptive properties than calcium phosphate. Therefore, one of ordinary skill in the art would not have simply substituted calcium phosphate for calcium sulfate in the material disclosed by *Ricci et al.*

Moreover, even if the alleged teachings of *Evans et al.* were applied to *Ricci et al.* exactly as suggested in the grounds for rejection, the claimed invention would not result. Namely, the alleged teachings of *Evans et al.* fails to cure the deficiencies previously noted above in connection with the requirements of amended claim 1.

Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 10 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Ricci et al.* in view of U.S. Patent No. 7,001,551 to Meredith (hereafter "*Meredith*") on the grounds set forth on page 5 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Meredith is cited as allegedly teaching inclusion of a growth factor in an implantable composition. However, even if the alleged teachings of *Meredith* were applied to *Ricci et al.* exactly as suggested in the grounds for rejection, the claimed invention would not result. Namely, the alleged teachings of *Meredith* fail to cure the deficiency of *Ricci et al.* with respect to the requirements of amended claim 1. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 16 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Ricci et al.* in view of U.S. 4,430,760 to Smestad (hereafter "*Smestad*") on the grounds set forth on page 5 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Smestad is cited on page 6 of the Official Action as allegedly teaching the inclusion of a porous casing or membrane to contain a filling material used to repair a bone defect. While not agreeing to the interpretation of *Smestad* given on the grounds for rejection, even if the alleged teachings of *Smestad* were to be applied to

Ricci et al. exactly as suggested in the grounds for rejection, the claimed invention would not result. Namely, the alleged teachings of *Smestad* fail to cure the deficiencies of *Ricci et al.* previously noted above in connection with the requirements of amended claim 1. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 46 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Evans et al.* on the grounds set forth on page 6 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Claim 46 depends from claim 43. The deficiencies of *Evans et al.* with respect to the requirements of amended claim 43 have been discussed above.

It is acknowledged that *Evans et al.* fails to disclose the claimed weight percentage of bio-compatible polymer in the composite matrix. Nevertheless, it is alleged that it would have been obvious to one of ordinary skill in the art to have provided the bio-compatible polymer and the claimed weight percentage through routine optimization. This assertion is respectfully traversed. Such "optimization" rationales are inappropriate when the prior art fails to recognize that the parameter being optimized is a result-effective variable. *Evans et al.* fails to recognize that the amount of polymer present in the composite material is a result effective variable. Thus, the rationale set forth in the grounds for rejection is improper. Reconsideration and withdrawal of the rejection is respectfully requested.

Regardless of whether the amount of bio-compatible polymer recited in claim 46 would have been obvious in view of *Evans et al.*, *Evans et al.* still fails to disclose, or even suggest, the composite matrix material defined by amended claim 43 for at

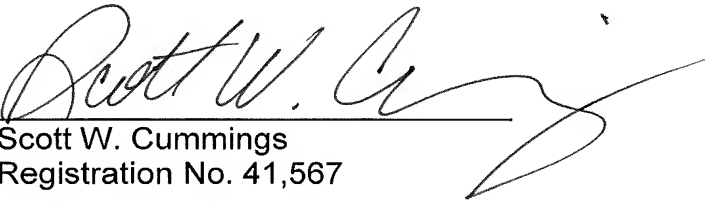
least the reasons noted above. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Respectfully submitted,

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